DETAILED ACTION

Claim Objections

1. The objection to claim 1 has been overcome by the amendment to the claim. The objection is hereby withdrawn.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 3, 5, 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Singhatat (US 2004/0133239 A1) in view of Wahl et al. (US 6,228,086 B1).

4. Regarding claims 1, 7 and 9, Singhatat teaches:

An implantable cross-pin (a pin shaped device {suture anchor 400; fig. 7}, capable of use as a cross-pin, see below) **comprising:**

an elongated member (anchor 400) **having a proximal end** (440)**, a distal end** (end oriented down in fig. 7, above the nose portion {distal end 450}; see marked up figure)**, and an outer surface;**

a nose member (distal end 450, ribbed section beyond the bottom of the proximal end) **extending out from the distal end of said elongated member having a proximal end and a distal end** (see marked up figure)**;**

an axial trough in the elongated member extending though the outer surface,

a guide wire opening in the distal end (at recess 480 and the first centrally aligned portion which attaches to the tunnel {oblique portion}) **of the nose member and**

concentric with the central longitudinal axis of the elongated member (see marked up figure)**;**

an interior tunnel (the oblique portion; see marked up figure) **having a passage with an enclosed circular perimeter in the nose member extending from the guide wire opening** (the portion concentric with the body) **and extending into the trough** (the portion 460) **such that the passage is in communication with the guide wire opening and the trough, the interior tunnel being obliquely oriented relative to the central longitudinal axis of the elongated member; and**

a guide wire (suture portion 410) **seated in the axial trough and extending through the interior tunnel and the guide wire opening;**

wherein the cross-pin comprises a biocompatible material [0040]**.**

A pin is defined as "a small, slender, often pointed piece of wood, metal, etc., used to fasten, support, or attach things" (Random House Dictionary, 2010). Both the suture anchor 400 of Singhatat and the nail 1 of Wahl et al. read upon this definition.

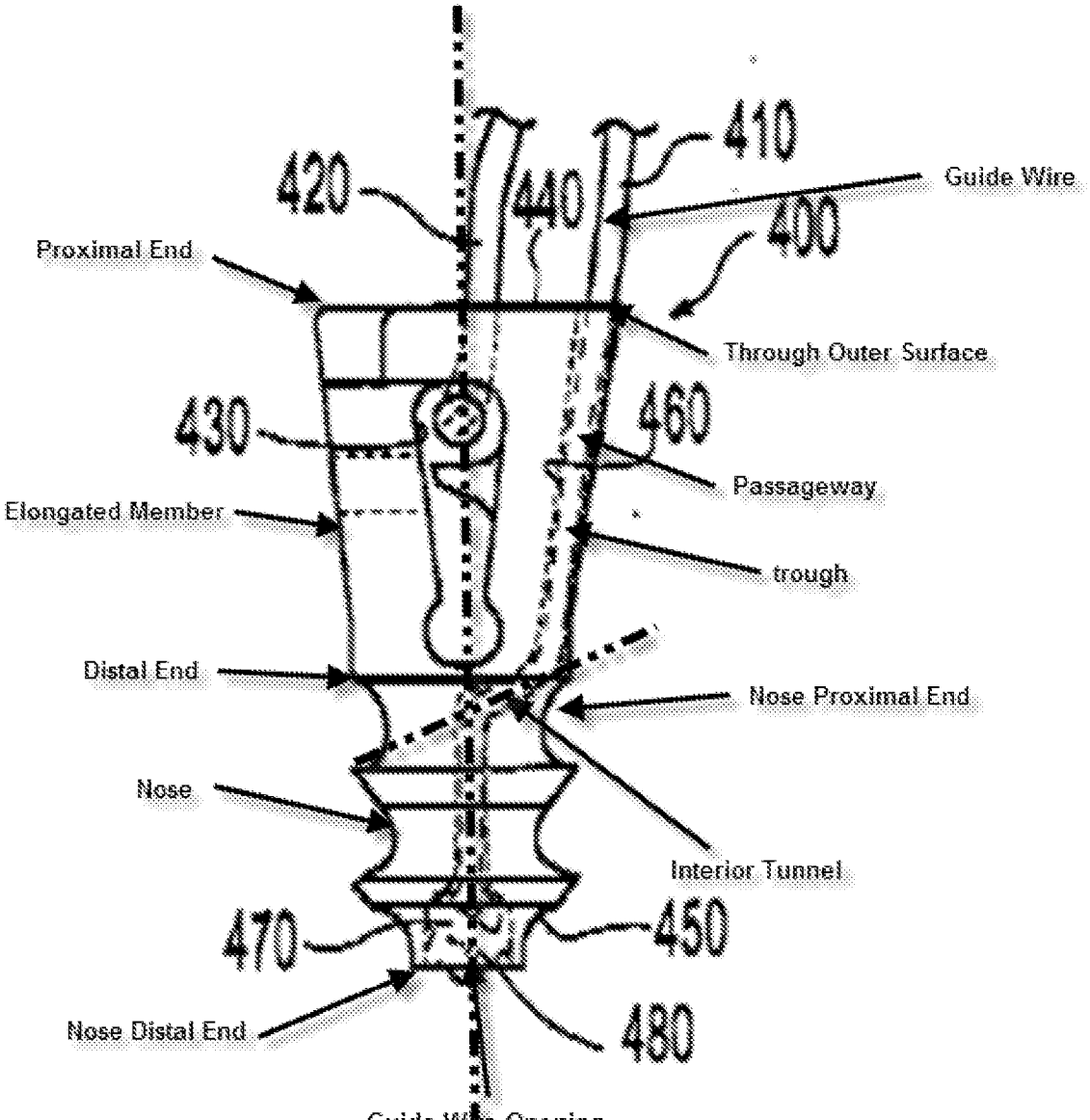


Fig. 7

Singhatat does not teach:

- The device to be **for use in an ACL repair procedure; nor**

- **The said trough having a proximal end, a distal end, a bottom, opposed ends, an open top, and a passageway.**

Wahl et al. teach an intramedullary nail having a wire groove 13 having a trough portion (best seen at figs. 1 and 2), and a tunnel (wire channel 13A) in the nose region. The tunnel has a portion which is oblique to the longitudinal axis of the device, and connects the trough 13 and guide wire opening 13A. (See marked up figure).

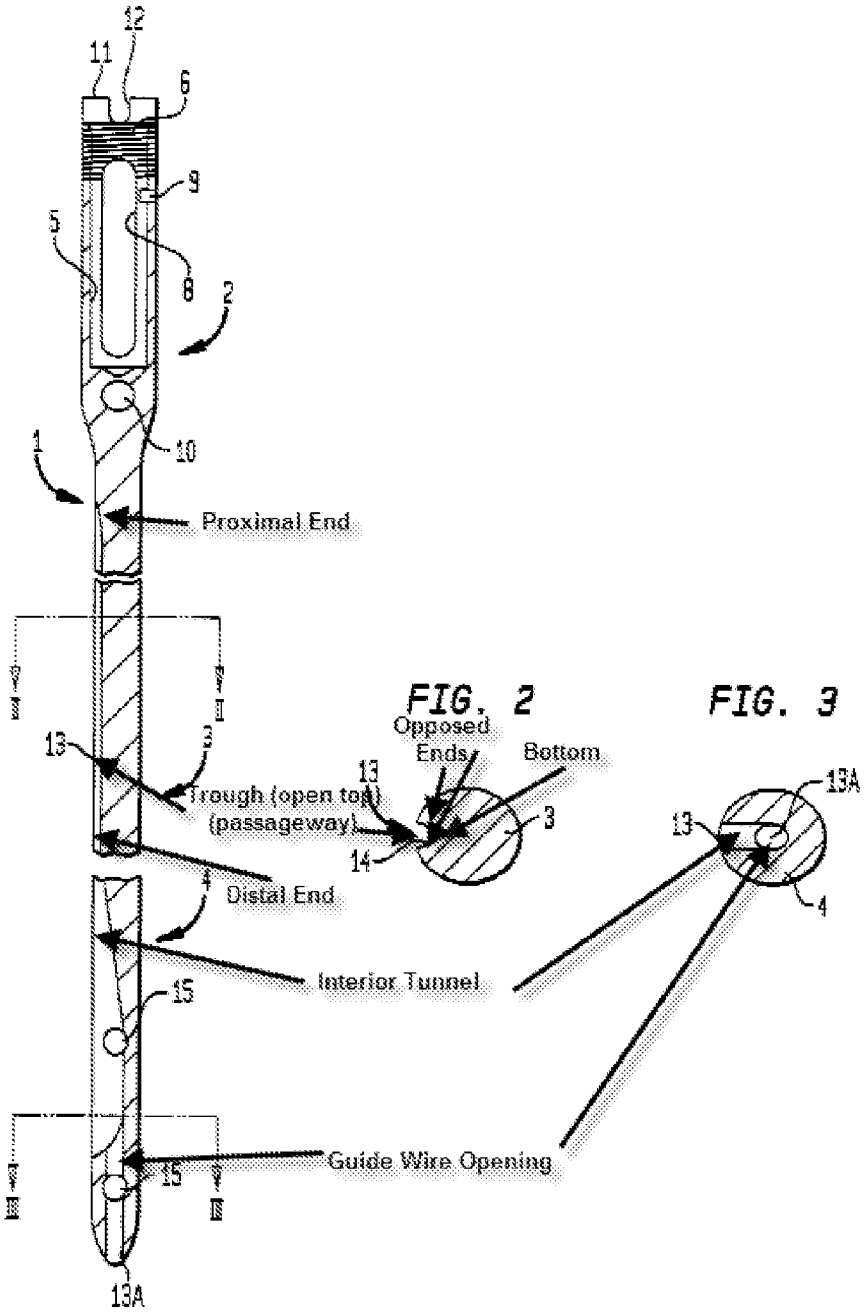
There is no reason that either the Singhatat device or the Wahl et al. device could not be used in an ACL repair procedure, and in fact, could not be used as a cross-pin. Were either of the devices threaded down a guide wire and driven into a drilled opening in the femur in which the tendon is prepared as shown in fig. 4 of the instant application, the device would cause identical fixation of the ACL graft, as produced by the instant invention (that operation described at [0019] of instant application).

It is unclear as to the purpose and criticality of the open trough design. The design appears to be merely design choice. Applicant's disclosure has shown advantages in his design to be that 1) the invention has reduced the need for multiple length implants [0003], 2) the implant can be revised/removed during the surgery [0003], and 3) the implant provides uni-cortical (single bone) fixation of a tendon. It is unclear how an open trough is required to allow any of these goals to be achieved.

Singhatat et al. disclose the claimed invention except for the trough being of an open design. It would have been an obvious matter of design choice to select an open trough design, like that of Wahl et al., since applicant has not disclosed that the open

trough design solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the closed trough design.

5. Regarding claims 3 and 5, Singhatat have taught the use of "any suitable biocompatible material" [0040] including resorbable polymers.



Response to Arguments

6. Applicant's arguments filed August 31, 2010 have been fully considered but they are not fully persuasive.

7. Initially, the amendment to claim 1 changed the scope of the location of the trough.

8. Further, the arguments did not overcome the design choice portion of the rejection.

9. Applicants arguments address intended uses of the prior art devices. The only functional limitation claimed is “implantable…for use in an ACL repair procedure”. Each, the Wahl device, the Singhatat device, and the combination thereof in which the trough of Singhatat was made to be an open structure is capable of being implanted into a bone to be used in an ACL repair. An appropriately sized hole being drilled into the bone allows such implantation.

10. Applicant states that "Wahl lacks a guidewire passage”. This is incorrect. A guidewire is capable of being passed through wire channel 13A.

11. Applicant states that "suture is not a guide wire, and moreover the suture in Singhatat is attached to the nose of the anchor; that is not how a guide wire works." Respectfully, a guide wire is a wire which is used for guiding. A suture is in the same configuration as a wire. There is no reason that a suture could not be used to guide the implant (move the implant in a desired direction by pulling the wire). Respectfully, “how applicant’s guide wire works” is not claimed. Even further, the combination device incorporates the wire bore 13A of Wahl, clearly adapted for receiving a wire, used in the

manner which applicant has intended. Physical limitations which differentiate the prior art suture from the guide wire are required to overcome the rejection based on guidewire arguments (i.e. rigidity, pointed tip).

12. Applicant states that due to the different uses of the Wahl and Singhatat devices, "there would be no reason to modify one with the structure of the other." MPEP 2141.01(a) states that "The examiner must determine what is 'analogous prior art' for the purpose of analyzing the obviousness of the subject matter at issue. Under the correct analysis, any need or problem known in the field of endeavor at the time of the invention and addressed by the patent [or application at issue] can provide a reason for combining the elements in the manner claimed. Thus a reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole."

The Wahl and Singhatat devices are both medical devices which teach trough designs for passing a wire therethrough. It would have been obvious to one with ordinary skill in the art at the time of the invention to review and incorporate various prior art medical devices for wire passage designs in devices for different intended uses.

13. Applicant states that if the combination of Singhatat and Wahl was made, the invention would not have been arrived at since the applicant's invention is a "cross pin." Applicant states that Singhatat is too short to serve as a cross pin and that the ribs in the design would weaken the device. In relying upon the limitation "cross pin" as a

cross pin, it is unclear which cross pin feature has not been provided by Singhatat. A "cross pin" is interpreted to be a pin which goes across a structure. It is unclear what the length of Singhatat is, or how Applicant has been able to interpret this length is too short for the purpose of a cross pin. No length has been disclosed in Singhatat. MPEP 2124 states that "proportions of features in a drawing are not evidence of actual proportions when drawings are not to scale" so the drawings may not be used to teach the length of the Singhatat device. Additionally, the ribs of the Singhatat device can be interpreted to *strengthen the device*. As opposed to applicant's interpretation of the ribs being an area of removed material, the ribs can be considered to be a region of increased material. Finally, the rejection was in view of the combination of Singhatat and Wahl, not Singhatat alone.

14. Applicant then asks "if one of skill in the art did modify Singhatat as per the Examiner's suggestion then would they put in a guide wire?" Seeing as the guide wire has been equated to the suture, the answer is answered by fig. 7 of Singhatat. The trough is designed to receive the suture which is capable of functioning as a guidewire. The functional limitations described in section 11 are again suggested.

15. Applicant states that the Singhatat device would lose its suture if a guidewire was passed therethrough. Since the suture is equated to the guidewire in the rejection, this is incorrect. See fig. 7 of Singhatat. The opposite end of the suture would continue to be retained. It is pointed out, however, that the instant invention is a device, not a method of use. Functional limitations of the instant invention are only required to be

capable of being carried out by a prior art device. They did not specifically have to be taught to be done.

Conclusion

16. **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID W. BATES whose telephone number is (571)270-7034. The examiner can normally be reached on Monday-Friday 9:00AM - 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tom Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. W. B./
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art Unit 3775